RAPID CITY REGIONAL HOSPITAL

Written 10CFR Part 21 Notification of Device Failure

Follow up to telephone notification given to NRC Operations Center on 7/19/05 (rpt # 41853)

Date of Written Report: July 20, 2005

Notification Submitted by: Edmund P. Cytacki, Ph..D., Radiation Safety Officer
John T. Vucurevich Cancer Care Institute
Rapid City Regional Hospital
353 Fairmont Blvd.
Rapid City, SD 57701

Written Report Sent to: NRC's Document Control Desk
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Facility Where Failure Occurred: John T. Vucurevich Cancer Care Institute
Rapid City Regional Hospital
353 Fairmont Blvd.
Rapid City, SD 57701
Medical Facility providing Cancer Radiation Therapy
USNRC lic. No. 40-00238-04

Date of Failure: January 6, 2005

Device that Failed: MicroSelectron V2 High Dose Rate Afterloader
Specific part: V-block assembly- broken flag wire

Device Supplier: Nucletron Corporation
8671 Robert Fulton Drive
Columbia, Maryland 21046
Tel. +1 410 312 4100
Fax. +1 410 312 4199

Description of Failure

At 7am on January 6, 2005 a cancer patient was being treated using the MicroSelectron High Dose Rate Unit. The treatment consisted of 31 channels, each with multiple dwell positions, and was divided into two parts of 18 and 13 channels respectively. The HDR unit operated normally during the morning QA checks and during the first 16 channels of part 1 of the treatment. After correctly completing treatment of all channel 16 dwell positions the HDR unit console reported an error and the check source and active source would not drive into channel 17. The errors reported were: code 18 "After retraction of the source the wire-in switch is actuated and the

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reference opto-pair is still obscured." and code 2042 "Program is interrupted, an error occurred." The treatment room door was opened and the physicist entered the room with a portable GM survey meter. The wall mounted survey meter in the room, the HDR unit mounted GM survey meter, and the portable GM survey meter carried by the physicist all indicated no radiation exposure above back ground was present in the treatment room. These readings confirmed that the source had returned to the in-(shielded) position as reported by the HDR unit console. After a radiation survey of the patient she was disconnected from the HDR unit and removed from the treatment room. The vendor, Nucletron, was telephoned and informed that a malfunction had occurred during a patient treatment. Procedures as directed by the Nucletron service person on the telephone were performed but the problem with the obscured opto-pair could not be fixed. The authorized user, who was present, informed the patient that the first part of her treatment had been completed correctly, but that the HDR unit was reporting an error code and that her treatment would be postponed and completed as soon as the HDR unit was repaired. A report was generated from the MicroSelectron console documenting that all dwell positions of the first 16 channels had been correctly treated.

Corrective Action

A service engineer from Nucletron arrived that afternoon and verified that the problem was a broken flag wire on the V-block assembly that contained the opto-pair. The next morning, January 7, 2005 a new redesigned V-block assembly from Nucletron arrived by express shipment. This part was installed by the Nucletron service engineer and the unit then worked correctly. After the Nucletron engineer's tests and the daily QA checks by the physicist were completed successfully, the patient treated as prescribed at 8:45am of that morning

Safety Concerns

In this specific failure there was no actual safety hazard and no 10CFR Part 21- "Reporting of Defects and Noncompliance" notification was immediately filed. The V-block opto-pair assembly is a safety part that monitors both the check cable and source cable in-out travel distance. Failure of this part should not cause an incorrect treatment nor inhibit the source return to the in-position. Also after a failure of this monitoring part it should not be possible to begin any further treatment until the part is replaced. From this report it can be seen that after the V-block failure that is exactly what happened in this incident. Channel 16 was treated with the correct dwell positions and times, and then the source retracted successfully to the in-(shielded) position. It was not possible drive the source from the in-position for further treatment until the V-block was replaced. The MicroSelctron unit performed safely and as it was designed after the V-block part failure.

However, after consulting with NRC staff, Rick Muños and Greg Morrall, I am filing this report as they suggested. Although it did not happen in this incident it might be possible for a failure of this type to constrict the source cable and prevent the safe return of the source to the in-position. Such an event would be a safety hazard to the patient and staff and so I am filing this report to alert other users of the MicrosSelectron unit of the possibility of this type of failure.

cc. Michael E. Gibbs, Vice President – Professional Services
Brad Johnson, Executive Director J.T.V. Cancer Care Institute